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Research Article

COMPARATIVE STUDY OF *DANTYADI LEPA* AND *SWARJIK KSHARADI LEPA* IN THE MANAGEMENT OF *STANAGRANTHI* W.S.R. TO FIBROADENOSIS OF BREAST

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ABSTRACT

Fibroadenosis, a benign breast condition common in women of reproductive age, is characterised by glandular and stromal tissue proliferation, leading to lumps. It is hormone-dependent, causing pain, swelling, and psychological distress. The rising global incidence emphasises its importance as a public health concern. **Review in Ayurveda and Modern Medicine:** In Ayurveda, fibroadenosis is similar to *'Stana-granthi*.' Modern treatment involves conservative and surgical approaches, which may have side effects or high recurrence rates, highlighting the need for alternative therapies. **Drug Review:** *Dantyadi Lepa* (DL) and *Swarjika Ksharadi Lepa* (SL) are Ayurvedic formulations with lump-reducing and scraping properties. DL contains *Danti, Chitraka* root, *Arka* latex, and *Kasisa*, while SL contains *Swarjika Kshara*, *MulakaKshara*, and *Shankha Bhasma*. Both target *Kapha* and *Vatadoshas* to address fibroadenosis. **Materials and Methods:** 40 patients were divided into two groups: Group 1 (DL) and Group 2 (SL), with both treatments applied twice daily for 2 months. Four follow-ups were conducted at 15-day intervals. **Observations and Results:** Group 1 (DL) showed 74.5 % cured, while Group 2 (SL) showed 67.4% cured. Overall, 71.2% of patients experienced significant symptom relief. **Discussion and Conclusion:** Both DL and SL were effective in reducing pain, swelling, and mass size, offering a promising, non-invasive alternative to conventional treatments. Their safety and efficacy suggest they are viable options for managing fibroadenosis.

INTRODUCTION

Fibroadenosis, also known as fibrocystic breast disease, is a common, non-cancerous condition affecting women, typically between the ages of 20 and 40. It is characterised by the proliferation of epithelial and stromal tissues in the breast, leading to the formation of palpable lumps or masses. This condition often causes discomfort, pain, and psychological distress, primarily due to fears of breast cancer. Conventional treatments, including hormone therapies, analgesics, and surgical excision, often fail to provide lasting relief and are associated with side effects such as hormonal imbalance, acne, weight gain, and a high recurrence rate due to the condition's hormone-dependent nature. These limitations highlight the need for safer, non-invasive alternatives.

In Ayurvedic literature, a similar condition, *Stana-granthi*, is described, where *'Granthi*' refers to glandular swelling in the breast. According to Ayurveda, this condition is caused by an imbalance of *Kapha* and *Vata doshas*, leading to the accumulation of vitiated *Doshas* and *Dushyas* (bodily tissues) in the *Mamsa dhatu* (muscle tissue). The resulting hard, knotty swellings are managed using formulations with *Lekhana* (scraping) and *Granthihara* (lump-reducing) properties.

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This study evaluates the effectiveness of two Ayurvedic formulations, *Dantyadi Lepa* and *Swarjika Ksharadi Lepa*, in managing fibroadenosis.

With fibroadenosis affecting 30-60% of women worldwide and its rising incidence in India, exploring alternative treatments is crucial. Ayurvedic formulations like *Dantyadi Lepa* and *Swarjika Ksharadi Lepa* present a promising option for effective and safe management of this condition, addressing both clinical outcomes and patient safety.

Patient Selection Criteria

Inclusion Criteria

1. Female patients aged 18–35 years, irrespective of marital status.
2. Patients presenting with classical symptoms of *Sthana Granthi* (Fibroadenosis of the breast), including:
   - Breast lump
   - Breast pain (mastalgia)
   - Nipple discharge (non-bloody) in one or both breasts.
3. Diagnosed cases of fibroadenosis confirmed by USG/USG mammography.
4. Patients with no significant psychological impact from the condition.

Diagnostic Criteria

1. **Clinical Presentation**
   - Presence of a palpable lump in the breast.
   - Pain or tenderness in the breast.
   - History of cyclical or non-cyclical symptoms associated with menstruation.
2. **Ultrasound (USG) Findings**
   - Hypoechoic or heterogeneous masses with smooth margins suggestive of benign breast disease.
3. **USG Mammography Findings** (if performed)
   - Non-calcified lesions or cystic changes consistent with fibroadenosis.

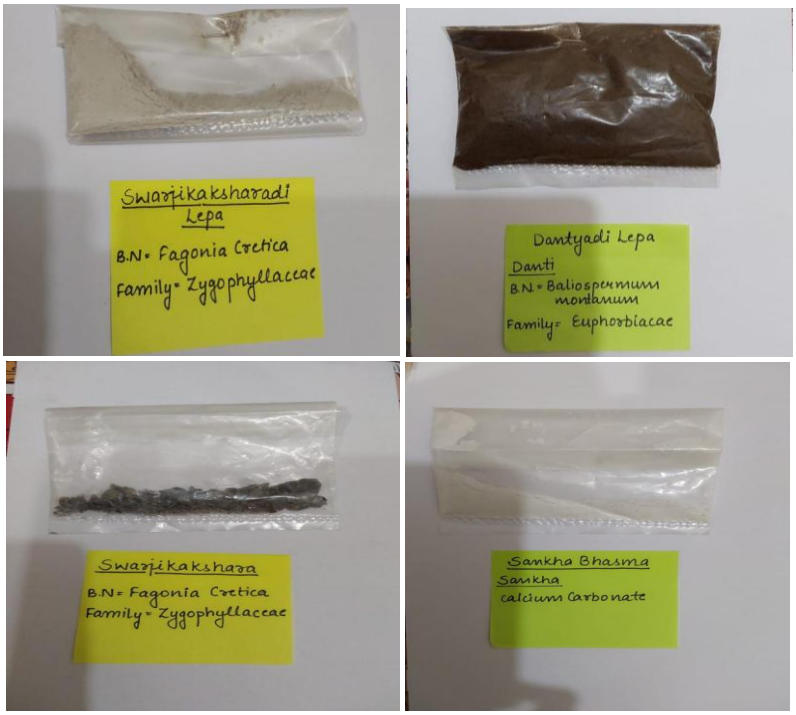
Selection of Drug[5,6]

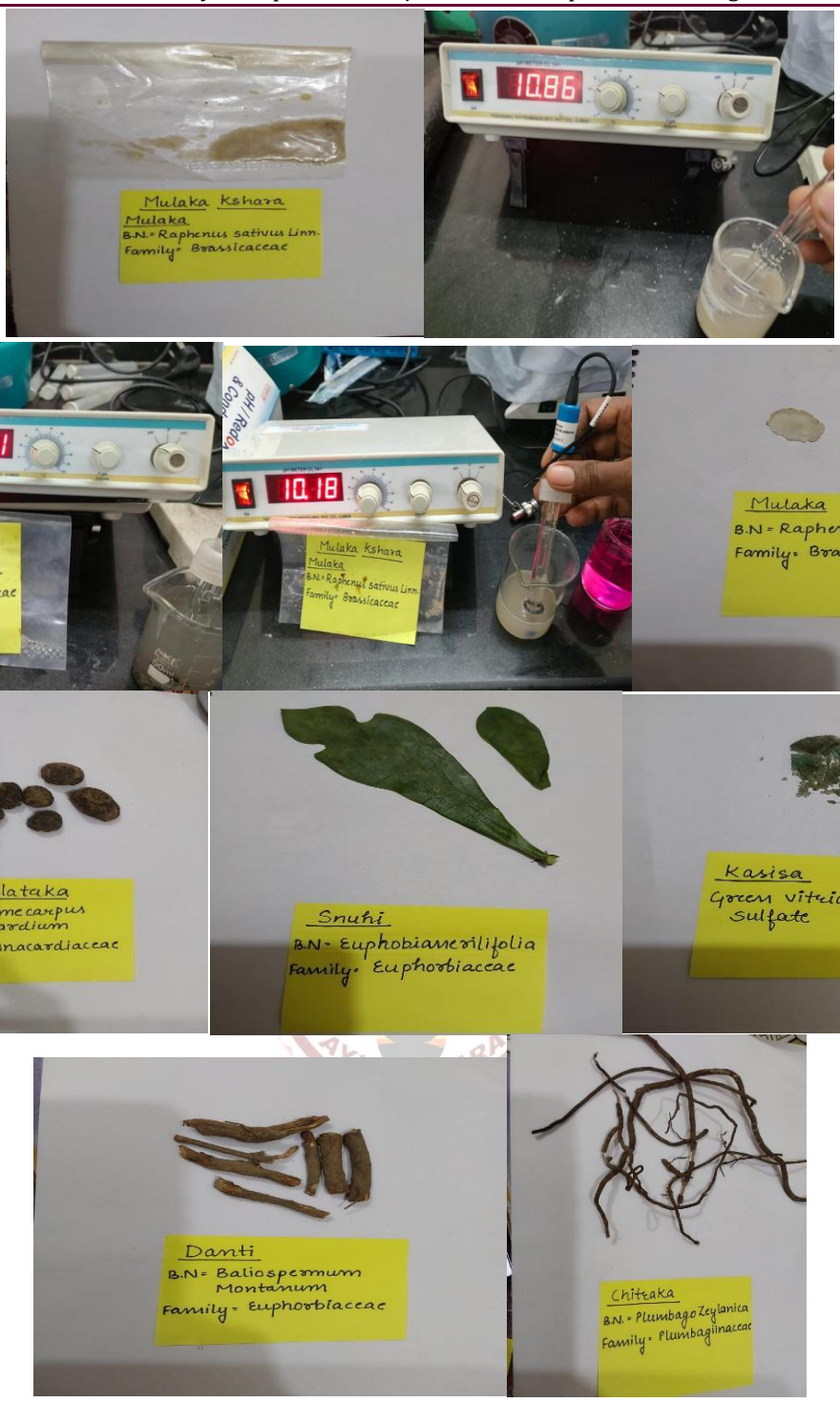
The selection of *Dantyadi Lepa* (DL) and *Swarjika Ksharadi Lepa* (SL) for managing fibroadenosis is based on their potent therapeutic properties described in Ayurvedic texts.

Drug Review[4]

Dantyadi Lepa (DL): A paste made from paste made from *Chitraka* (*Plumbago zeylanica L.*), *Snuhi* (*Euphorbia nerifolia L.*), *Arka* (*Calotropis procera*), *Bhallataka* (*Semecarpus anacardium*), *Kasisa* (green vitriol or ferrous sulphate), *Guda* (jaggery). DL exhibits *Tikshna* (sharp), *Ushna* (hot), and *Tikta* (bitter) properties. It balances *Kapha* and *Vatadoshas*, promotes *Lekhana* (scraping), and reduces lump size by thinning *Mamsa Dhatu* and inhibiting fibrotic tissue growth.

Swarjika Ksharadi Lepa (SL): Composed of *Swarjika Kshara (Dhanvayasa) Botanical name: Fagonia Cretica Linn.*), *MulakaKshara*, and (Botanical name: *Raphenus sativus Linn.), Shankha Bhasma*, SL's *Tikshna* (sharp), *Katu* (pungent), and *Ushna Virya* (hot potency) properties break down hard tissues and soften fibroadenotic lumps. It reduces *Kapha*-dominated swelling and compactness by loosening stromal tissue and inducing apoptotic changes, making the lumps softer and easier to treat.





***Lepa* and its application**

Preparation of *Lepa* and applying *Lepa* on the affected breast

After application of *Lepa* kept for drying After removal of *Lepa*

MATERIALS AND METHODS[5]

The clinical study on benign breast disease (BBD) followed a meticulous methodology to ensure accurate results. The study involved 40 female patients aged 18-35 years, presenting with symptoms such as breast lumps, pain, or nipple discharge. These patients were selected from the *Prasuti Tantra* OPD of S.S. Hospital, BHU, Varanasi. The inclusion criteria ensured that only those diagnosed with benign conditions, like fibroadenosis confirmed by ultrasonography (USG) or mammography, were part of the study. Exclusion criteria were equally stringent, disqualifying any patient with suspicious lumps, skin allergies, open wounds, or neoplasms.

Patients underwent a thorough demographic and medical history analysis, covering aspects like age, education, socioeconomic status, and psychological conditions. The history was detailed, including past illnesses, surgical history, menstrual and obstetric history, and contraception use. A general and systemic examination was conducted, utilising *Ashtavidha* and *Dashavidha Pariksha*, which are traditional Ayurvedic diagnostic methods. These examinations included evaluating the pulse, stool, urine, tongue, speech, skin, and overall appearance, along with specific systemic checks for the central nervous, respiratory, cardiovascular, gastrointestinal, and genitourinary systems.

Breast examinations were critical, focusing on detecting pathologies like fibroadenoma, fibroadenosis, or carcinoma. The examination included inspection and palpation, where healthcare providers systematically checked for lumps or abnormalities. This was complemented by laboratory investigations, both routine and specific. Routine tests included complete blood count (CBC), fasting blood sugar (FBS), C-reactive protein (CRP), and serum prolactin levels. Specific tests like mammography, ultrasonography, and fine needle aspiration cytology (FNAC) were conducted before and after therapy as required.

The methodology emphasised the comprehensive assessment of each patient, combining subjective and objective criteria. Parameters like pain, tenderness, mobility, stiffness, consistency, and the size of the breast mass were carefully monitored. These were scored on a grading scale, with the study particularly focusing on pain related to the menstrual cycle and other symptoms such as itching, burning, and discharge. The study's approach was both traditional and scientific, combining Ayurvedic diagnostic methods with modern medical practices to ensure a holistic evaluation of benign breast disease in young women.

Subjective and Objective Parameters and its Gradations[5]

Study Objectives

1. To evaluate the general pathophysiology of *Sthana Granthi* in both Ayurveda and modern medical sciences.
2. To assess the clinical efficacy of the local application of *Dantyadi Lepa* and *Swarjika Ksharadi Lepa* in the management of *Sthana Granthi*, with special reference to fibroadenosis.
3. To compare the therapeutic efficacy of *Dantyadi Lepa* and *Swarjika Ksharadi Lepa* in managing *Sthana Granthi*.
4. To standardize both *Lepas* as per pharmaceutical and analytical parameters for ensuring quality, safety, and efficacy.

Subjective Parameters and Gradations[7,8,9]

1. **Pain (*Vedana*)**
   - Grade 0: No pain
   - Grade 1: Mild pain, occasional, not interfering with daily activities.
   - Grade 2: Moderate pain, frequent, affecting daily activities but manageable.
   - Grade 3: Severe pain, constant, significantly interfering with daily activities.
   - Grade 4: Very severe

Table 1: Intensity of *Vedana* (Pain) of the breast during different follow-ups in both the groups (n=40)

Groups	*Vedana* (Pain)	BT		F1		F2		F3		AT	
		No.	%	No.	%	No.	%	No.	%	No.	%
Group 1 (DL)	Nil	0	0.0	0	0.0	2	10	6	30	14	70
	Mild	0	0.0	7	35	10	50	13	65	5	25
	Moderate	8	40	12	60	8	40	1	5	1	5
	Severe	12	60	1	5	0	0.0	0	0.0	0	0.0
	Very Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Group 2 (SL)	Nil	1	5	1	5.3	1	5.3	7	36.7	11	57.8
	Mild	2	10	4	21	11	58.3	7	37.7	7	36.7
	Moderate	14	70	12	63	7	37.1	5	26.3	1	5.3
	Severe	2	10	2	10.6	0	0.0	0	0.0	0	0.0
	Very severe	1	5	0	0.0	0	0.0	0	0.0	0	0.0
Between the group comparison Mann-Whitney test		Z=1.660 P=0.097 (NS)		Z=.0490 P=0.624 (NS)		Z=.0796 P=0.426 (NS)		Z=.0471 P=0.638 (NS)		Z=1.479 P=0.139 (NS)	

2. Swelling *(Shopha)*

- Grade 0: No swelling
- Grade 1: Mild localized swelling
- Grade 2: Moderate swelling with discomfort.
- Grade 3: Severe swelling, affecting mobility or causing significant discomfort.

Table 2: Intensity of *Shopha* (Tenderness) of the breast during different follow-ups in both groups(n=40)

Groups	*Shopha* (Tenderness)	BT		F1		F2		F3		AT	
		No.	%	No.	%	No.	%	No.	%	No.	%
Group 1 (DL)	Nil	0	0.0	4	20	7	35	11	55	19	95
	Mild	5	25	8	40	11	55	8	40	1	5
	Moderate	13	65	8	40	2	10	1	5	0	0.0
	Severe	2	10	0	0.0	0	0.0	0	0.0	0	0.0
Group 2 (SL)	Nil	4	20	3	15.8	6	31.6	12	63.2	15	78.9
	Mild	7	35	11	57.9	8	42.1	6	31.6	4	21.1
	Moderate	7	35	5	26.3	5	26.3	1	5.3	0	0.0
	Severe	2	10	0	0.0	0	0.0	0	0.0	0	0.0
Between the group comparison Mann-Whitney test		Z=1.660 P=0.097 (NS)		Z=.490 P=0.624 (NS)		Z=.796 P=0.426 (NS)		Z=.471 P=0.638 (NS)		Z=1.479 P=0.139 (NS)	

3. Stiffness *(Stambha)*

- Grade 0: No stiffness
- Grade 1: Mild stiffness, occasional
- Grade 2: Moderate stiffness, frequent
- Grade 3: Severe stiffness, constant

Table 3: Intensity of *Stambha* (Mobility-Stiffness) of the breast during different follow-ups in both the group (n=40)

Groups	*Stambha* (Mobility-Stiffness)	BT		F1		F2		F3		AT	
		No.	%	No.	%	No.	%	No.	%	No.	%
Group 1 (DL)	Nil	2	10	8	40	16	80	19	95	20	100
	Mild	11	55	12	60	4	20	1	5	0	0.0
	Moderate	7	35	0	0.0	0	0.0	0	0.0	0	0.0
	Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Group 2 (SK)	Nil	7	35	8	42.1	9	47.4	11	57.9	12	63.2
	Mild	5	25	5	26.3	5	26.3	6	31.6	7	36.8
	Moderate	6	30	6	31.6	5	26.3	2	10.5	0	0.0
	Severe	2	10	0	0.0	0	0.0	0	0.0	0	0.0
Between the group comparison Mann-Whitney test		Z=.224 P=0.823 (NS)		Z=.978 P=0.328 (NS)		Z=2.380 P=0.017 (S)		Z=2.736 P=0.006 (S)		Z=2.958 P=0.003 (S)	

4. Breast Pain During Menstrual Cycle (MC)

- Grade 0: No pain during MC.
- Grade 1: During menses
- Grade 2: Before and after menses

Table 4: Incidence of Breast Pain about the menstrual cycle in both groups (n=40) (BT-AT)

Groups	Breast pain relation to the Menstrual cycle	BT		AT	
		No.	%	No.	%
Group 1 (DL)	No pain	12	60	19	95
	During menses	4	20	0	0.0
	Before and after menses	4	20	1	5.0
Group 2 (SL)	No pain	10	50	17	89.5
	During menses	6	30	2	10.5
	Before and after menses	4	20	0	0.0
Between the group comparison Mann-Whitney test		Z=0.481 P=0.631 (NS)		Z=0.578 P=0.563 (NS)	

Objective Parameters and Gradations

1. Consistency of Mass

- Grade 0: Normal breast tissue
- Grade 1: Soft consistency
- Grade 2: Rubbery/Firm consistency
- Grade 3: Hard consistency

Table 5: Consistency of mass/cyst in total cases (n=40) and both groups

Groups	Consistency of mass/cyst	BT		AT	
		No.	%	No.	%
Group 1 (DL)	NAD	3	15	11	55
	Soft	8	40	7	35
	Rubbery	8	40	2	10
	Hard	1	5	0	0.0

Group 2 (SL)	NAD	5	25	15	78.9
	Soft	9	45	1	5.3
	Rubbery	3	15	2	10.5
	Hard	3	15	1	5.3
Between the group comparison Mann-Whitney test		Z=0.999 P=0.318 (NS)		Z=1.334 P=0.182 (NS)	

2. Size of Mass (Measured by USG in cm)

- Grade 0: No mass
- Grade 1: Lump size < 1 cm
- Grade 2: Lump size < 2 cm
- Grade 3: Lump size < 3 cm

Table 6: Size of mass/cyst in the breast both groups(n=40)

Groups	Size of mass/cyst	BT		AT	
		No.	%	No.	%
Group 1(DL)	NAD	4	20	12	60
	<1 cm	6	30	5	25
	<2 cm	4	20	2	10
	<3 cm	6	30	0	5
Group 2(SL)	NAD	6	30	9	47.4
	<1 cm	4	20	4	21.1
	<2 cm	4	20	3	15.8
	<3 cm	6	30	3	15.8
Between the group comparison Mann-Whitney test		Z=0.280 P=0.780 (NS)		Z=1.065 P=0.287 (NS)	

3. Fibroadenotic Changes on USG

- Grade 0: No abnormalities.
- Grade 1: Minimal cystic changes.
- Grade 2: Multiple cystic changes with smooth margins.
- Grade 3: Complex cystic changes or irregular margins

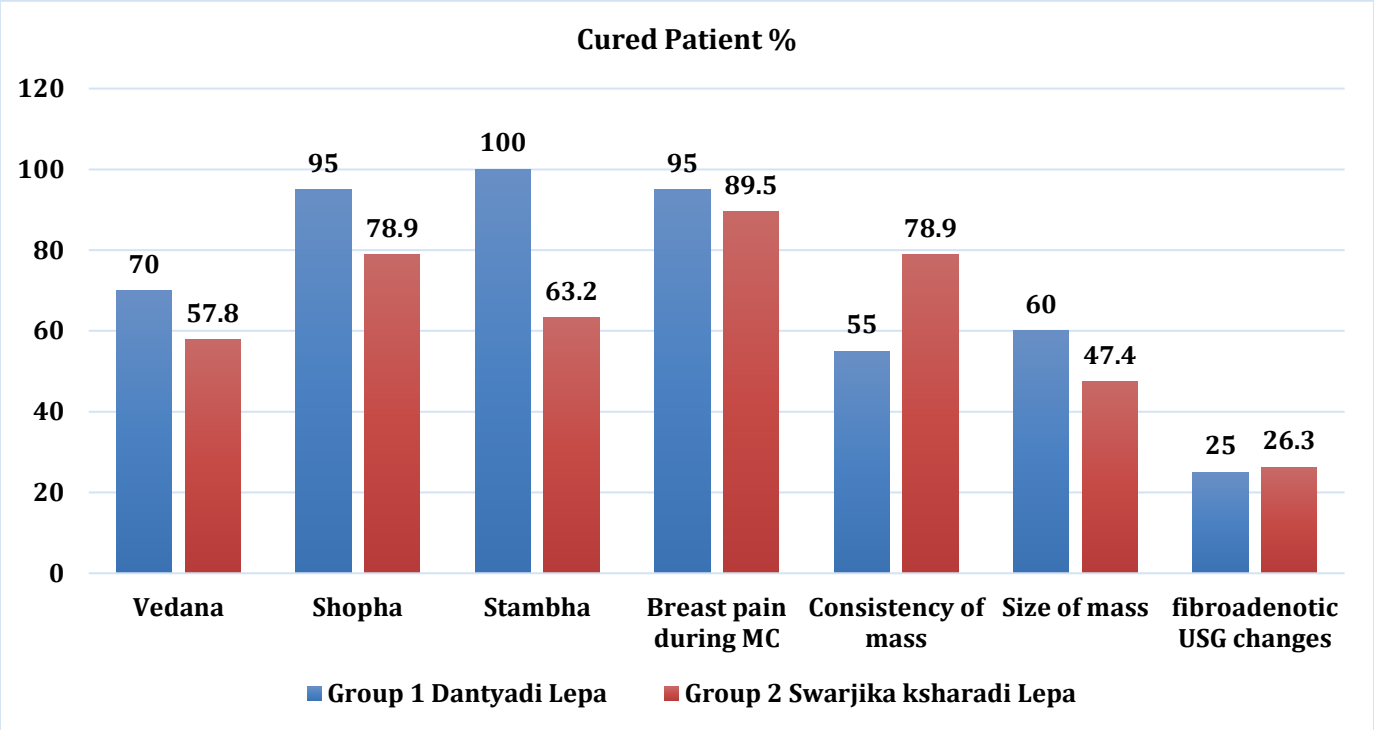
Table 7: Pattern of USG Breast Changes in both groups(n=40)

Groups	USG Breast	BT		AT	
		No.	%	No.	%
Group 1 (DL)	1	1	5	5	25
	2	2	10	10	50
	3	17	85	5	25
Group 2 (SL)	0	1	5	5	26.3
	1	6	30	9	47.3
	2	13	65	5	26.3
Between the group comparison Mann-Whitney test		Z=1.361 P=0.173 (NS)		Z= 3.976 P= 0.000 (S)	

OBSERVATION

Dantyadi Lepa (DL) demonstrated superior results in relieving *Vedana* (pain), *Shopha* (swelling), *Daha* (burning sensation), *Stambha* (stiffness), and breast pain associated with the menstrual cycle, achieving complete relief in 74.5% of patients. *Swarjika Ksharadi Lepa* (SL) was more effective in improving consistency and fibroadenotic ultrasound changes, with 67.4% achieving complete relief and a notable improvement in hardness, transforming *Katina guna* (hard quality) to *Mrdu guna* (soft quality) due to its *Tiksna, ushna* properties, *Katu rasa,* and *Ushna virya*. USG findings revealed significant improvements in both groups, with DL reducing Grade 3 fibroadenotic changes from 85% to 25% and SL increasing normal scans from 5% to 26.3%, indicating both treatments effectively reduced fibroadenotic changes.

Graph 1: Parameters and Cured patient % in Both groups at the end of follow-ups

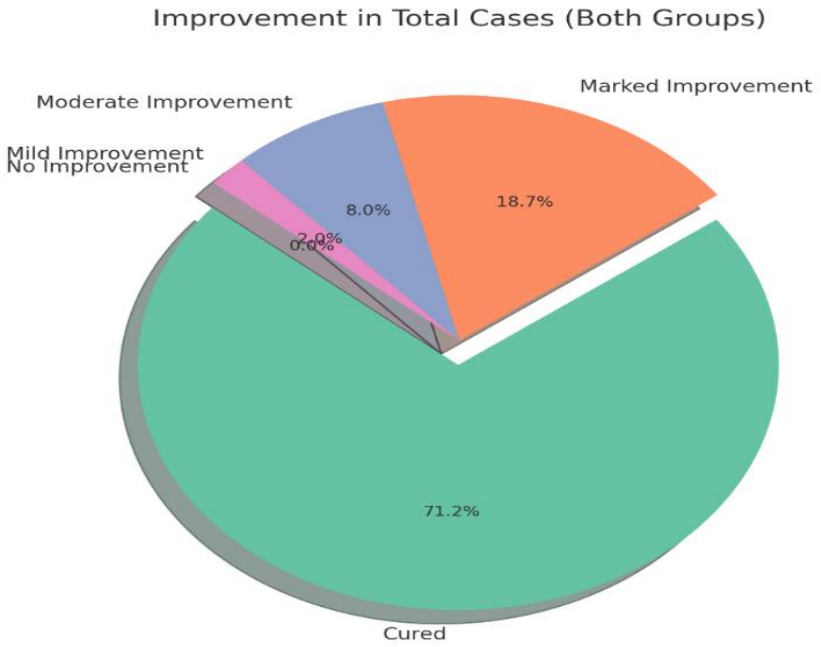


Here is the tabular representation of the data from the bar chart

Parameter	Group 1 (*Dantyadi Lepa)* (%)	Group 2 (*Swarjika Ksharadi Lepa*) (%)
Vedana (Pain)	70	57.8
Shopha (Swelling)	95	78.9
Stambha (Stiffness)	100	63.2
Breast pain during MC	95	89.5
Consistency of mass	55	78.9
Size of mass	60	47.4
Fibroadenotic USG changes	25	26.3

Overall, both treatments were effective in reducing fibroadenotic changes.

Graph 2: Results in total cases at the end of follow-ups



Here is the table representation of the data from the pie chart:

Improvement Category	Percentage (%)
Cured	71.2
Marked Improvement	18.7
Moderate Improvement	8.0
Mild Improvement	2.0
No Improvement	0.0

DISCUSSION

This study evaluates the effectiveness of *Dantyadi Lepa* (DL) and *Swarjika Ksharadi Lepa* (SL) in managing fibroadenosis, highlighting their significant therapeutic potential. Both formulations are based on Ayurvedic principles, targeting the underlying imbalances of *Kapha* and *Vatadoshas*, which are considered key in the development of fibroadenosis. DL is particularly effective in reducing pain, swelling, and the size of breast masses due to its *Lekhana* (scraping) properties, which help break down excess tissue. SL, on the other hand, excels at softening the consistency of the masses, transforming their hardness and improving tissue texture.

Both treatments offer comprehensive relief by addressing the root causes of fibroadenosis, with no reported side effects, making them a safer and cost-effective alternative to modern therapies, which often come with adverse effects and high recurrence rates. The combination of *Kapha-Vata* balancing properties, along with the potent phytoconstituents in both formulations, makes them promising options for women seeking non-invasive and long-lasting solutions for benign breast conditions. Further clinical trials and research will help solidify their place in mainstream treatment for fibroadenosis.

CONCLUSION

The study concludes that *Dantyadi Lepa* and *Swarjika Ksharadi Lepa* are effective, safe, and promising alternatives to conventional fibroadenosis treatments. With *Dantyadi Lepa* showing slightly superior results in *Vedana* (pain), *Shopha* (swelling), *Daha* (burning sensation), *Stambha* (stiffness), and breast pain associated with the menstrual cycle, both formulations can significantly reduce fibroadenotic symptoms and improve patient outcomes without any adverse effects. These findings encourage further research into the long-term efficacy and broader application of Ayurvedic treatments in breast disease management.

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